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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,684	06/06/2005	Kathleen Grace Mountjoy	BSWV-P01-007	3069

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EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,684	MOUNTJOY ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

It is noted that the many of the claims are in improper form because multiple dependencies. See MPEP § 608.01(n). It is recommended that Applicants amend the claims otherwise they cannot be treated upon the merits.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7 (in part), 15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to methods of assessment, predicting risk or diagnosis in a subject comprising measuring a melanocortin peptide in a sample obtained from said subject and comparison of the measured value with a reference value.

Group II, claim(s) 5, 7 (in part), 15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to screening medicaments for adverse reactions in a subject to whom the medicament has been administered comprising measuring the melanocortin peptide in a sample obtained from said subject and comparison of the measured value with a reference value.

Group III, claim(s) 6, 7 (in part), 15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to screening foods and/or diets for adverse reactions in a subject to whom the medicament has been administered comprising measuring the melanocortin peptide in a sample obtained from said subject and comparison of the measured value with a reference value.

Group IV, claim(s) 8, 14-15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to methods of assessing feeding and/or weight gain pattern in a subject comprising the measurement of at least two melanocortin peptides in a sample obtained

from said subject, the calculation of the ratio of the measured melanocortin peptides and comparison of the ratio with a reference value.

Group V, claim(s) 9-11, 14-15 (in part), 16, 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to methods of assessment, predicting risk or diagnosis in a subject comprising measuring two melanocortin peptides in a sample obtained from said subject and comparison of the ratio with a reference value.

Group VI, claim(s) 12, 14-15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to screening medicaments for adverse reactions in a subject to whom the medicament has been administered comprising measuring at least two melanocortin peptides in a sample obtained from said subject and comparison of the ratio with a reference value.

Group VII, claim(s) 13, 14-15 (in part), 17-20 (in part), 23 (in part), 25 (in part), 29-33 (in part), drawn to screening foods and/or diets for adverse reactions in a subject to whom the medicament has been administered comprising measuring the two melanocortin peptides in a sample obtained from said subject and comparison of the ratio with a reference value.

Group VIII, claim(s) 21, 23 (in part), 24, 25 (in part), 29-33 (in part), drawn to methods of monitoring treatment in a subject or determining the melanocortin peptide status of a sample comprising contacting a sample obtained from the subject having such treatment or sample with a biological response system wherein the resulting profile of response parameters is indicative of the effect of such treatment or indicates the melanocortin peptide status of the sample.

Group IX, claim(s) 22, 23 (in part), 25 (in part), 29-33 (in part), drawn to methods of assessing the risk comprising analyzing the profile of response parameters in a sample from a test subject by comparing it with (i) the profile of a sample with a normal subject and (ii) the profile of a sample from an obese subject or a subject with an imbalance in energy homeostasis and/or disturbance in feeding/weight gain pattern, wherein resemblance of the profile of the sample obtained from the test subject to that of the profile in (ii) above is indicative of that subject being at risk of developing obesity or developing and/or having an imbalance in energy homeostasis and/or disturbance in feeding/weight gain pattern.

Group X, claim(s) 26, 27, 28, 29-33 (in part), drawn to methods of screening for a compound that acts as an agonist or antagonist of a melanocortin receptor comprising treating a biological response system with a test compound and measuring the resulting profile of response parameters that are indicative of agonist or antagonist activity to the melanocortin receptor or exposing a biological response system to a test compound and measuring the resulting profile of response parameters that are indicative of the desired response for the treatment of obesity.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: first, PCT rules provide for the examination of the first claimed product, the first claimed method of making said product and the first claimed method of using said product, not multiple processes. In addition, Group I, drawn to methods of assessment, predicting risk or diagnosis in a subject comprising measuring a melanocortin peptide in a sample obtained from said subject and comparison of the measured value with a reference value whereas in Group II, which is a method for screening medicaments and Group III, which is a method for screening foods both require the presence of the medicament (II) or the food (III), thus do not share the same technical features with Group I. Groups IV-VII do not share a special technical feature with Group I because unlike Group I, which is limited to the measurement of one melanocortin peptide, Groups IV-VII encompass methods comprising the measurement of at least two melanocortin peptides, and calculating the ratio of the measured melanocortin peptides and comparison of the value of that ratio with a reference value. Group VIII is drawn to methods of monitoring treatment in a subject or determining the melanocortin peptide status of a sample, Group IX is drawn to risk assessment comprising analyzing a profile of response parameters in a subject and Group X is drawn to screening methods that further require the analysis of a biological response system to agonist or antagonist activity to melanocortin receptors, whereas Group I is drawn to diagnosis.

This application contains claims directed to more than one species: Heat Shock Protein Homologues (recited in claim 33) of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

HEAT SHOCK PROTEIN HOMOLOGUES

1. glyceraldehyde-3-phosphate-dehydrogenase
2. aldo-keto reductase
3. citrate synthase
4. creatine kinase
5. pyruvate synthase alpha-chain
6. f1 ATPase beta-chain
7. tubulin beta-chain
8. proteins involved in the melanocortin peptidergic axis
9. proteins involved in signaling pathways
10. membrane-bound proteins.

The claims are deemed to correspond to the species listed above in the following manner:

33

The following claim(s) are generic: 32.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each additional homologue represents a separate contribution to the art; art anticipating one species will not anticipate another.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER